October 14, 2020

VIA ECF

The Honorable Theodore D. Chuang
United States District Judge
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 245A
Greenbelt, MD 20770

Re: *American College of Obstetricians and Gynecologists v. U.S. Food and Drug Administration*, Case No. 20-1320

Dear Judge Chuang,

We write pursuant to § II.A of the May 28, 2020 Case Management Order (Dkt. 22) and in advance of the October 15 status conference. On October 8, the Supreme Court issued an order on Defendants' application for a stay pending appeal, stating that "a more comprehensive record would aid th[e] Court's review" and that the Court would therefore "hold the Government's application in abeyance to permit the District Court to promptly consider a motion by the Government to dissolve, modify, or stay the injunction, including on the ground that relevant circumstances have changed." *Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34, 592 U.S. _____ (2020), slip. op. at 1. "Without indicating [its] view on the merits," the Court noted in its one-paragraph order Defendants' argument that the injunction is "overly broad, given that it applies nationwide and for an indefinite duration regardless of the improving conditions in any individual State." *Id.* at 1. This suggests that the Court is particularly interested in further record development regarding the status of the COVID-19 pandemic and whether the scope of the injunction was proper.

In opposing any further motion by Defendants to dissolve, modify, or stay the injunction, Plaintiffs intend to submit additional evidence regarding, *inter alia*, the ongoing nationwide threat of COVID-19. In addition, Plaintiffs believe that answers from Defendants to a limited set of targeted questions is necessary to ensure that this Court and the Supreme Court have a "comprehensive record" as to whether nationwide injunctive relief continues to be proper. Specifically, Plaintiffs ask this Court to direct Defendants to submit written responses to the following questions along with any motion to stay, modify or dissolve the injunction, and/or that the Court schedule Plaintiffs' response to any such motion only after Defendants respond to the following questions:

1. Do the ETASU C suspensions Defendants described in Dkt. 78 apply nationwide?

2. Do Defendants' representations to the Court in Dkt. 78 remain accurate and/or has the U.S. Food and Drug Administration ("FDA") suspended any additional ETASU requirements during the public health emergency ("PHE")? Please describe any additional suspensions and the circumstances under which they were issued.

3. On October 2, Defendant Azar renewed the COVID-19 PHE nationwide, effective October 23, 2020 (when the prior COVID-19 PHE determination would have automatically expired). Did Secretary Azar consider limiting the COVID-19 PHE to only certain states, as permitted under section 319 of the Public Health Service Act?

4. In Dkt. 78, Defendants stated that "the HHS Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine exception in section 802(54)(D) of the Controlled Substances Act applies during the public health emergency to all schedule II-V controlled substances and in all areas of the United States." Please confirm that the HHS Secretary has authority to limit the telemedicine exception under section 802(54)(D) of the Controlled Substances Act to only patients located in certain areas of the United States, but that Secretary Azar, with the concurrence of the Acting DEA Administrator, instead determined that it should extend to patients in all areas of the United States for as long as the PHE is in effect.

5. In March 2020, Defendant HHS's Centers for Medicare & Medicaid Services announced that it would temporarily expand Medicare coverage to include a broader range of telemedicine services under section 1135 waiver authority and the Coronavirus Preparedness and Response Supplemental Appropriations Act. Please confirm that the HHS Secretary has authority to grant state-level 1135 waivers, but that Secretary Azar instead determined that this coverage expansion should extend to patients in all areas of the United States for as long as the PHE is in effect.

6. In March 2020, Defendant FDA issued new guidance giving sponsors of clinical trial studies discretion to forgo in-person visits otherwise required by the study's approved protocol during the PHE. Please confirm that FDA had discretion to limit this guidance only to trial participants located in certain areas of the United States, but instead determined that this non-enforcement policy should extend to trial participants in all areas of the United States. Please also confirm whether this guidance remains in effect nationwide.

7. In March 2020, Defendant HHS's Office for Civil Rights (OCR) announced that it would not enforce certain potential penalties for Health Insurance Portability and Accountability Act (HIPAA) violations against healthcare providers that serve patients through everyday communications technologies, such as FaceTime and Zoom, during the COVID-19 nationwide PHE. Please confirm that OCR had discretion to limit this non-enforcement guidance only to health care providers located in certain areas of the United States, but instead determined that this non-enforcement policy should extend to providers in all areas of the United States. Please also confirm whether this guidance remains in effect nationwide.

8. In June 2020, Defendant FDA issued new guidance relaxing requirements for prescription-drug samples to permit patients to receive such medication by mail or common carrier at their homes in order to ensure patient and healthcare provider safety during the PHE. Please confirm that FDA had discretion to limit this guidance only to patients located in certain

areas of the United States, but instead determined that this non-enforcement policy should extend to patients in all areas of the United States. Please also confirm whether this guidance remains in effect nationwide.

9. Do Defendants contend that any harms have occurred since the injunction took effect? To which, if any, person or entity? On what evidence, if any, is any contention of harm based?

Plaintiffs notified Defendants of these questions on the morning of October 14 and requested that they be in a position to state their position on these requests at the October 15 case management conference.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5.

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